

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

C.A. No. 21-1015 (GBW)

SAREPTA THERAPEUTICS, INC. and  
UNIVERSITY OF WESTERN AUSTRALIA,

Defendant/Counter-Plaintiff,

v.

NIPPON SHINYAKU CO., LTD.  
and NS PHARMA, INC.

Plaintiff/Counter-Defendants.

REDACTED - PUBLIC VERSION

**LETTER TO THE HONORABLE GREGORY B. WILLIAMS  
FROM SAREPTA THERAPEUTICS, INC. SEEKING LEAVE TO AMEND  
ITS ANSWER AND COUNTERCLAIMS**

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Dear Judge Williams

Pursuant to Fed. R. Civ. P. 15(a) & 16(b) and Paragraph 5 of the Scheduling Order (D.I. 143), Sarepta Therapeutics Inc. (“Sarepta”) respectfully seeks leave to amend its Answer and Counterclaims to assert an affirmative defense and counterclaim for inequitable conduct against Nippon Shinyaku, Ltd. (“NS”).

## **I. FACTUAL BACKGROUND**

Sarepta’s inequitable conduct claims are based on two separate acts: (1) NS’s affirmative misrepresentations to the United States Patent and Trademark Office (“USPTO”) regarding the alleged superiority of the claimed subject matter over the prior art, and submission of “cherry-picked” information [REDACTED] and (2) withholding a material reference from the USPTO. Sarepta provides facts related to each ground as follows:

### **A. Misrepresentations Concerning “Superiority” of the Claimed Subject Matter**

NS has asserted seven patents (“NS Patents”) against Sarepta. These patents claim morpholino antisense oligomers (“PMOs”) targeting positions 36 to 60 of exon 53. Ex. 1, ¶¶98-121. Before filing the NS Patents, [REDACTED] many prior art antisense PMOs targeting exon 53, including “PMO-A” (targeting positions 35 to 59, just *one* base position shifted from the claimed PMOs) and “PMO-G” (targeting positions 30 to 59, characterized by NS as a “top performer” during patent prosecution). PMO-A and PMO-G were both reported by Popplewell and coworkers (“Popplewell paper”). Ex. 1, ¶¶187-89.

NS nevertheless obtained patents in the US, Europe, and Japan by arguing that the claimed oligomers are allegedly “superior” to those reported in the Popplewell paper. For example, in the US, its representative Mr. Zhengyu Feng asserted that the claimed oligomers have “superior skipping activity” over “the top performer taught in Popplewell”—PMO-G. *Id.*, ¶¶126-40. The same argument was presented in Japan by an attorney at a law firm called Abe, Ikubo, and Katayama (“AIK”). *Id.*, ¶¶157-59. In Europe, NS submitted experimental data and a declaration from Mr. Toshihiro Ueda, who attested that the claimed oligomers have “superior skipping activity” over another PMO in the Popplewell paper. *Id.*, ¶¶141-56.

But NS *repeatedly* omitted data from its patents, [REDACTED]

[REDACTED] to secure patent allowance.

[REDACTED] data was *not* submitted to the USPTO. *Id.*, ¶204.

Mr. Watanabe and Mr. Feng [REDACTED] Mr. Feng’s repeated representations that the claimed oligomers were “superior” to PMO-G. Ex. 1, ¶¶205-208. [REDACTED]

[REDACTED] the conclusion he drew from it, were not submitted to the USPTO. *Id.*, ¶208.

NS’s practice of cherry-picking data extends to its attacks on other patents and further supports an intent to deceive the USPTO. In opposing a patent licensed to Sarepta in Europe, NS

submitted two declarations from Mr. Watanabe, attesting that the “the invention cannot be worked successfully over the whole scope of the claim.” Ex. 1, ¶¶209-13. [REDACTED]

[REDACTED] His declarations were submitted by Mr. Feng to the USPTO, but [REDACTED]. *Id.*

## **B. Failure to Submit the Sazani Paper**

[REDACTED] a publication by Sazani and coworkers (“Sazani paper”) establishing, for the first time, the favorable safety profile of an antisense PMO with a particular 5’-end modification in primates—a chemistry that NS later copied into the claims of the NS Patents. *See id.*, ¶¶185, 102-104. [REDACTED]

[REDACTED] ut Mr. Watanabe *never* submitted it to the USPTO. *Id.*, ¶186.

## **II. ARGUMENTS**

### **A. Good Cause Exists Under Rule 16(b) for Granting Sarepta’s Motion**

“Good cause exists when the Schedule cannot reasonably be met despite the diligence of the party seeking the extension.” *ICU Med., Inc. v. RyMed Techs, Inc.*, 674 F. Supp. 2d 574, 577. (D. Del. 2009). It is particularly true where, as here, the allegations are based on “a new set of facts obtained and confirmed during discovery which took place after the Scheduling Order’s deadline for amended pleadings.” *Id.* at 578; *Roquette Frères v. SPI Pharma, Inc.*, 2009 WL 1444835, at \*5 (D. Del. May 21, 2009). Here, NS did not produce documents disclosing critical omitted information until June 21, 2023—nearly three months after the deadline to amend the pleadings and five months after the substantial completion deadline. Further, NS did not make Mr. Watanabe available for deposition until June 26-27, 2023. During that deposition, Sarepta confirmed [REDACTED]

[REDACTED]. *See Roquette*, 2009 WL 1444835, at \*5 (it is “appropriate” for the defendant to confirm inequitable conduct allegations through discovery before filing its motion).

### **B. There Is No Undue Delay, Bad Faith, or Prejudice Against NS**

“Amendment should ordinarily be permitted absent a showing of undue delay, bad faith or dilatory motive on the part of the movant,” and “undue prejudice to the opposing party.” *ICU*, 674 F. Supp. 2d at 577. Here, there is no undue delay: Sarepta obtained supportive testimony within a week of obtaining key documents produced at the eleventh hour, approached NS regarding its proposed amendment within two weeks of Mr. Watanabe’s deposition, and filed this motion the day NS indicated its opposition to the motion. *See BigBand Networks, Inc. v. Imagine Comm’n’s, Inc.*, 2010 WL 2898286, at \*2 (D. Del. Jul. 20, 2010) (no undue delay for a motion to amend filed “within weeks of learning the information it seeks to add through the depositions”). Sarepta also acted in good faith, prudently and diligently gathering facts necessary to plead its inequitable conduct claims with detail as required under Rule 9(b). *See Intervet Inc., Boehringer Ingelheim Vetmedica, Inc.*, 2012 WL 4808427, at \*1 (D. Del. Oct. 9, 2012) (“unsupported charges of inequitable conduct are disfavored by the Federal Circuit”) (citation omitted); *Roquette*, 2009 WL 1444835, at \*5 (citing Rule 9(b)’s “particularity requirement”).

NS will not suffer from any prejudice. Information relevant to Sarepta’s inequitable conduct claims was in NS’s possession long before this litigation, including [REDACTED]

[REDACTED] *See Roquette*, 2009 WL 1444835, at \*5 (no prejudice because “[i]nformation regarding the inventors’ knowledge and what they did or did not do regarding the patent specification and their representations to the PTO would primarily be within the control” of a non-movant). Sarepta’s inequitable conduct claims do not require any modification to the current schedule because no additional discovery is needed.

### C. Sarepta’s Amendments Will Not Be Futile

Sarepta’s proposed amendments will not be futile because they satisfy the pleading standard under Rule 9(b). *See Intervet*, 2012 WL 4808427, at \*1 (amendment not futile because it “alleges facts from which the Court may infer that the inventors were aware of the prior art and its materiality, as well as their deceptive intent”). Sarepta has identified in over 130 proposed paragraphs the specific “who, what, when, where, and how of the material misrepresentation or omission committed before” the USPTO and provided “sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive” the USPTO. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327-29 (Fed. Cir. 2009).

Sarepta’s amendments regarding “superiority” satisfies the *Exergen* standard (Ex. 1, ¶¶214-26):

- **Who:** [REDACTED]
- **What, When, Where, and How:** During prosecution of the NS Patents, by affirmatively misrepresenting the alleged superiority of the claimed oligomers versus the prior art on July 22, 2016 and February 27, 2017, when [REDACTED] But for NS’s repeated misrepresentations about the “superior skipping activity” of the claimed oligomers, the NS Patents would not have issued.
- **Intent to Deceive:** [REDACTED] During prosecution of the NS Patents, Mr. Watanabe, through Mr. Feng, wrongly alleged that the claimed oligomers were superior to the prior art, even though [REDACTED] Indeed, [REDACTED] succeeded in obtaining and challenging patents in multiple jurisdictions, including the US, [REDACTED] The single most reasonable inference is that the conduct [REDACTED] was intended to deceive the USPTO to obtain patent claims covering Sarepta’s product.

Sarepta’s amendments regarding the Sazani paper satisfies *Exergen* (Ex. 1, ¶¶227-31):

- **Who:** Mr. Watanabe, a named inventor.
- **What, When, Where, and How:** Withheld the Sazani paper from submission to the USPTO [REDACTED] Had the USPTO been aware of the Sazani paper, it would not have allowed the NS Patents.
- **Intent to Deceive:** [REDACTED] [REDACTED], Mr. Watanabe never submitted the Sazani paper to the USPTO.

### III. CONCLUSION

For the foregoing reasons, Sarepta respectfully requests that the Court grant its motion for leave to amend its Answer and Counterclaims.

Respectfully,

*/s/ Megan E. Dellinger*

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MED/bac

cc: All Counsel of Record (via electronic mail)